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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,790	11/13/2001	Yasuhisa Fukui	48977-DIV (71965)	1076

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EDWARDS & ANGELL, LLP  
P.O. BOX 9169  
BOSTON, MA 02209

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/29/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/007,790

Applicant(s)

Fukui et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 12, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-26 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) 22-26 ~~is~~/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-21 ~~is~~/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/257,069.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6-8 6) ☐ Other:

## **DETAILED ACTION**

### **Preliminary Amendment**

- 1) Acknowledgment is made of Applicants' preliminary amendment filed 11/13/01 (paper no. 5).

### **Election**

- 2) Acknowledgment is made of Applicants' election filed 02/10/03 (paper no. 10), without traverse of invention I, claims 18-22, in response to the restriction requirement mailed 01/08/03 (paper no. 9).

### **Status of Claims**

- 3) Claims 1-17 have been canceled via the preliminary amendment filed 11/13/01.

Claims 18-26 are pending.

Claims 23-26 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Inclusion of claim 22 in invention I was an inadvertent error. Since claim 22 depends from a non-existent claim and is drawn to a method non-pertinent to the subject matter of invention I, claim 22 is hereby withdrawn from examination. The Office regrets any inconvenience caused to Applicants.

Claims 18-21 are under examination. An Action on the Merits for these claims is issued.

### **Sequence Listing**

- 4) Acknowledgment is made of Applicants' letter with regard to the CRF/sequence listing filed 05/12/03 (paper no. 13) with the statement that it is identical with the one submitted in the parent case, SN 09/257,069.

### **Priority**

- 5) The instant application claims priority to applications, 10-330395, filed 11/20/1998 and 10-348065, filed 12/08/98, both filed in Japan. The Office acknowledges Applicants' submission of the priority documents in the parent case.

### **Drawings**

- 6) The drawings are objected to under 37 C.F.R. 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 15). Correction is required. Applicant is

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asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

#### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

##### *A. Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36*

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

##### *B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.*

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

##### *Timing of Corrections*

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in  
ABANDONMENT of the application.

#### **Specification - Informalities**

7) The instant specification is objected to for the following reasons:

(a) The first paragraph of the specification lacks the priority information as indicated above under the section 'Priority'.

(b) The instant specification incorporates subject matter into the patent application by reference to a hyperlink. For example, see last paragraph on page 33. However, attempts to incorporate subject matter into the patent application by reference to an active hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01. Such embedded active hyperlinks and/or other forms of browser-executable code therefore require deletion.

#### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

8) Claims 18-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 18 is vague in the recitation 'variable region thereof', because it is unclear what structure is encompassed in this region. Since only the monoclonal antibody is required to specifically recognize the recited triphosphate, the structure, functions or the purpose of the 'variable region' is not clear.

(b) Claim 19 improperly depends from a canceled claim, claim 15.

(c) Claim 18 is indefinite and confusing. Step (a) of claim 18 recites a monoclonal antibody that specifically recognizes 'Phosphatidylinositol-3,4,5-triphosphate'. Step (b) recites that the antibody binds to an antigenic determinant on 'said phosphatidylinositol-3,4,5-triphosphate'. But the latter part of part (a) of claim 18 recites that the monoclonal antibody is reacted with 'phosphatidylinositol-3,4,5-3,4,5-triphosphate'. Step (b) of claim 18 includes the recitation 'detecting the binding ..... between said antibody ..... and said triphosphate'. It is unclear whether the antecedence for 'said triphosphate' comes from 'Phosphatidylinositol-3,4,5-triphosphate' or 'phosphatidylinositol-3,4,5-3,4,5-triphosphate'.

(d) Claim 20 is vague, indefinite and confusing in the recitation: 'antibody comprises an immunoglobulin'. The scope of the 'antibody' which is recited to comprise 'immunoglobulin' is not understood, since the art recognizes an 'antibody' to be synonymous with a 'immunoglobulin'. See page 9 of *Glossary of Biochemistry and Molecular Biology*. Revised Edition. Glick DM, Portland Press, London, 1997.

(e) Claim 21 has improper antecedence in the recitation 'said immunoglobulin'. Claim 21 depends from claim 19, which does not recite any immunoglobulin.

(f) Claim 20 lacks antecedence in between the recitation 'recognizes phosphatidylinositol-3,4,5-triphosphate' (see line 8). Since the recitation already appears in the earlier part of the claim, for proper antecedence, it is suggested that Applicants replace the recitation with -- recognizes the phosphatidylinositol-3,4,5-triphosphate--.

(g) Claim 18 is vague because of the confusing recitations: 'phosphatidylinositol-3,4,5-3,4,5-triphosphate' and 'Phosphatidylinositol-3,4,5-triphosphate'.

#### **Objection(s) / Suggestion(s)**

9) To be consistent with the claim language used in claims 19, 20 and part (b) of claim 18, in line 3 of claim 18, it is suggested that Applicants replace the recitation 'Phosphatidylinositol-3,4,5-triphosphate' with --'phosphatidylinositol-3,4,5-triphosphate'--.

#### **Remarks**

10) Claims 18-21 stand rejected.

11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center is able to receive facsimile transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9306.

12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on

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Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER